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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shuji Hinuma

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EXAMINER

STOICA, ELLY GERALD

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,676	Applicant(s) HINUMA ET AL.	
	Examiner ELLY-GERALD STOICA	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. In the amendment filed 03/21/2009 Applicant amended claims 8 and 24 and canceled claim 9. Claims 8 and 24 are pending and currently examined.

Withdrawn claim rejections

2. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn is moot since the claim has been cancelled.
3. The rejection of claim 9 under 35 U.S.C. 102(e) as being anticipated by Goddard et al. (U.S. Pat. No. 6,949,528) is moot since the claim has been cancelled.

Maintained claim rejections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8 and 24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in claim 8 it is not clear *what* binding property is measured in 1a). A remedial wording suggested would be

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measuring the binding property of the lysophosphatidic acid to the EDG2 receptor.

Same for part b). The part h) of the claim doesn't connect to the rest of the claim.

Claim 24 has steps a and b, which already exist in claim 8. Therefore, the claim is indefinite, since it is not clear how the steps relate to one another, nor when they should be performed. Also, in 28(b), "determining" is not a method step.

As such the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (U.S. Pat. 6, 485,922, 11/26/2002) in view of Lynch et al. (U. S. Pat. No. 7,169,818) and Inoue CK (Semin. Nephrol., 22,415-422, 2002) for the reasons of record.

On page 9 of the Remarks Applicant argues that nothing in Lynch and Inoue teaches or suggests a connection between Edg-2 and mesangial cell growth. The arguments were carefully considered but not found persuasive because as iterated in the previous Office action, Lynch et al. taught that Lysophosphatidic Acid (LPA) signals through three G protein coupled receptors (EDG-2, 4 and 7). As such, a small, finite numbers of

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choices are put forth by Lynch et al. for the skilled artisan to try. Moreover, Inoue et al. describe that EDG-2 and EDG-4 mRNA is abundantly expressed in primary cultured human mesangial cells. Thus, the choice of receptors is narrowed to just two members of the EDG family. The fact is that Erickson et al. teach a method for identifying compounds which modulate the activity of any EDG receptors. In order to identify compounds that modulate mesangial cell growth, a person of ordinary skill in the art would have had to try just two receptors, EDG-4 and EDG-2 which had high levels of mRNA expression in primary mesangial cells as shown above. The motivation is always present to a skilled artisan that uses known options available to him to optimize a process or a formulation, as eloquently expressed in the Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 550 US, 82 USPQ2d 1385 (2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

On pages 10-11 of the Remarks Applicant argues that the effects of the LPA are mediated through three EDG receptors and there is no express teaching that the effects of LPA on mesangial cells are through EDG-2. The arguments were carefully considered but not found persuasive because as presented supra, the three receptors mentioned constitute a finite number of possibilities to be tried as expressed in the KSR decision.

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On page 11 of the Remarks Applicant argues there is no reasonable expectation that the methods of Erickson et al. and Lynch et al. could be extrapolated to work in animal tests. The arguments were carefully considered but not found persuasive because the next logical step to try after finding a modulator of a receptor is to test its action in vivo and this has been the modus operandi of the drug discovery. Before testing any drug in vivo the test is performed on a target cell in vitro and if successful, it is reasonable to expect positive results at the next step, in vivo testing. Therefore, it would have been obvious for a modulator found active in vitro to be tested in an animal model in vivo. Since Applicant recognized in the previous Office actions that mesangial cells are linked to nephropathies, it would have been perfectly obvious to test for the modulators involvement in these diseases.

8. Claims 8 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Pat. 6,875,757 04/05/2005) in view of Lynch et al. (U. S. Pat. No. 7,169,818) and in further view of Inoue CK (Semin. Nephrol., 22,415-422, 2002) for the reasons of record.

On page 13 of the Remarks Applicant argues that Lynch et al. and Inoue et al. do not tie together the physiological effects of LPA on mesangial cells to EDG-2.

As presented in the previous office action, Miller teaches a method of modulating LPA activity on an LPA receptor which includes providing a compound which has activity as an LPA receptor antagonist and contacting an LPA receptor with the compound under conditions effective to inhibit LPA-induced activity of the LPA receptor.

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Any activity through EDG-2 is in the wake of LPA binding to the EDG-2 receptor and thus the effects on any cells are expected to still be able to be blocked, irrespective of which cells that harbor the EDG-2 receptor. The arguments were carefully considered but not found persuasive because as presented supra, the combined references would have prompted a person of ordinary skill in the art to at least try the method of Miller et al. and Lynch et al. for modulation of mesangial cell growth based on the EDG-2 or 4 mRNA expression in primary mesangial cells as indicated by Inoue et al.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/

Primary Examiner, Art Unit 1647